

**§ 310.502 Certain drugs accorded new drug status through rulemaking procedures.**

(a) The drugs listed in this paragraph have been determined by rulemaking procedures to be new drugs within the meaning of section 201(p) of the act. An approved new drug application under section 505 of the act and part 314 of this chapter is required for marketing the following drugs:

- (1) Aerosol drug products for human use containing 1,1,1-trichloroethane.
- (2) Aerosol drug products containing zirconium.
- (3) Amphetamines (amphetamine, dextroamphetamine, and their salts, and levamfetamine and its salts) for human use.
- (4) Camphorated oil drug products.
- (5) Certain halogenated salicylanilides (tribromsalan (TBS, 3,4',5-tribromosalicylanilide), dibromsalan (DBS, 4', 5-dibromosalicylanilide), metabromsalan (MBS, 3, 5-dibromosalicylanilide), and 3,3', 4,5'-tetrachlorosalicylanilide (TC-SA)) as an ingredient in drug products.
- (6) Chloroform used as an ingredient (active or inactive) in drug products.
- (7) Cobalt preparations intended for use by man.
- (8) Intrauterine devices for human use for the purpose of contraception that incorporate heavy metals, drugs, or other active substances.
- (9) Oral prenatal drugs containing fluorides intended for human use.
- (10) Parenteral drug products in plastic containers.
- (11) Sterilization of drugs by irradiation.
- (12) Sweet spirits of nitre drug products.
- (13) Thorium dioxide for drug use.
- (14) Timed release dosage forms.
- (15) Vinyl chloride as an ingredient, including propellant, in aerosol drug products.

(b) [Reserved]

[62 FR 12084, Mar. 14, 1997, as amended at 64 FR 401, Jan. 5, 1999]

**§ 310.503 Requirements regarding certain radioactive drugs.**

(a) On January 8, 1963 (28 FR 183), the Commissioner of Food and Drugs exempted investigational radioactive new drugs from part 312 of this chapter pro-

vided they were shipped in complete conformity with the regulations issued by the Nuclear Regulatory Commission. This exemption also applied to investigational radioactive biologics.

(b) It is the opinion of the Nuclear Regulatory Commission, and the Food and Drug Administration that this exemption should not apply for certain specific drugs and that these drugs should be appropriately labeled for uses for which safety and effectiveness can be demonstrated by new drug applications or through licensing under the Public Health Service Act (42 U.S.C. 262 *et seq.*) in the case of biologics. Continued distribution under the investigational exemption when the drugs are intended for established uses will not be permitted.

(c) Based on its experience in regulating investigational radioactive pharmaceuticals, the Nuclear Regulatory Commission has compiled a list of reactor-produced isotopes for which it considers that applicants may reasonably be expected to submit adequate evidence of safety and effectiveness for use as recommended in appropriate labeling. Such use may include, among others, the uses in this tabulation:

Isotope	Chemical form	Use
Chromium 51 ...	Chromate .....	Spleen scans.
Do .....	.....do .....	Placenta localization.
Do .....	.....do .....	Red blood cell labeling and survival studies.
Do .....	Labeled human serum albumin.	Gastrointestinal protein loss studies.
Do .....	.....do .....	Placenta localization.
Do .....	Labeled red blood cells.	Do.
Cobalt 58 or Cobalt 60.	Labeled cyanocobalamin.	Intestinal absorption studies.
Gold 198 .....	Colloidal .....	Liver scans.
Do .....	.....do .....	Intracavitary treatment of pleural effusions and/or ascites.
Do .....	.....do .....	Interstitial treatment of cancer.
Iodine 131 .....	Iodide .....	Diagnosis of thyroid functions.
Do .....	.....do .....	Thyroid scans.
Do .....	.....do .....	Treatment of hyperthyroidism and/or cardiac dysfunction.
Do .....	.....do .....	Treatment of thyroid carcinoma.
Do .....	Iodinated human serum albumin.	Blood volume determinations.